



[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; New proposed collection; comment request

Environmental Science Formative Research Methodology Studies for the National Children's Study

SUMMARY:

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Child Health and Human Development (NICHD), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

PROPOSED COLLECTION:

Title: Environmental Science Formative Research Methodology Studies for the National Children's Study (NCS). *Type of Information Collection Request:* Generic Clearance.

Need and Use of Information Collection: The Children's Health Act of 2000 (Public Law 106-310) states:

(a) *PURPOSE.*—*It is the purpose of this section to authorize the National Institute of Child Health and Human Development* to conduct a national longitudinal study of environmental influences (including physical, chemical, biological, and psychosocial) on children's health and development.*

(b) *IN GENERAL.*—*The Director of the National Institute of Child Health and Human Development* shall establish a consortium of representatives from appropriate Federal agencies (including the Centers for Disease Control and Prevention, the Environmental Protection Agency) to—*

(1) plan, develop, and implement a prospective cohort study, from birth to adulthood, to evaluate the effects of both chronic and intermittent exposures on child health and human development; and

(2) investigate basic mechanisms of developmental disorders and environmental factors,

both risk and protective, that influence health and developmental processes.

(c) REQUIREMENT.—The study under subsection (b) shall—

(1) incorporate behavioral, emotional, educational, and contextual consequences to enable a complete assessment of the physical, chemical, biological, and psychosocial environmental influences on children’s well-being;

(2) gather data on environmental influences and outcomes on diverse populations of children, which may include the consideration of prenatal exposures; and

(3) consider health disparities among children, which may include the consideration of prenatal exposures.

To fulfill the requirements of the Children’s Health Act, the results of formative research will be used to maximize the efficiency (measured by scientific robustness, participant and infrastructure burden, and cost) of environmental sample collection procedures and technology, storage procedures, accompanying questionnaires, and assays, and thereby inform data collection methodologies for the National Children’s Study (NCS) Vanguard and Main Studies. With this submission, the NCS seeks to obtain OMB’s generic clearance to collect environmental samples from homes and child care settings, and conduct accompanying short surveys related to the physical and chemical environment.

The NCS has obtained OMB’s generic clearance to conduct survey and instrument design and administration, focus groups, cognitive interviews, and health and social service provider feedback information collection surrounding outreach, recruitment and retention (OMB # 0925-0590; Expiration Date 9/30/2014). Under separate notice, the NCS is also requesting generic clearance to conduct formative research featuring biospecimen and physical measures (OMB # 0925-0647, Expiration Date 1/31/2015), neurodevelopmental (pending clearance), and study logistic (pending clearance) information collection. Separate and distinct generic clearances are requested to facilitate the efficiency of submissions and review of these projects as requested by the Office of Information and Regulatory Affairs.

BACKGROUND:

The National Children’s Study is a prospective, national longitudinal study of the interaction between environment, genetics on child health and development. The Study defines “environment” broadly, taking a number of natural and man-made environmental, biological, genetic, and psychosocial factors into account. By studying children through

their different phases of growth and development, researchers will be better able to understand the role these factors have on health and disease. Findings from the Study will be made available as the research progresses, making potential benefits known to the public as soon as possible. The National Children's Study is led by a consortium of federal partners: the U.S. Department of Health and Human Services (including the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development and the National Institute of Environmental Health Sciences of the National Institutes of Health and the Centers for Disease Control and Prevention), and the U.S. Environmental Protection Agency.

To conduct the detailed preparation needed for a study of this size and complexity, the NCS was designed to include a preliminary pilot study known as the Vanguard Study. The purpose of the Vanguard Study is to assess the feasibility, acceptability, and cost of the recruitment strategy, study procedures, and outcome assessments that are to be used in the NCS Main Study. The Vanguard Study begins prior to the NCS Main Study and will run in parallel with the Main Study. At every phase of the NCS, the multiple methodological studies conducted during the Vanguard phase will inform the implementation and analysis plan for the Main Study.

In this request, the NCS is requesting generic approval from OMB for formative research activities relating to the collection, storage, management, and assay of environmental samples and accompanying questionnaires. The results from these formative research projects will inform the feasibility (scientific robustness), acceptability (burden to participants and study logistics) and cost of NCS Vanguard and Main Study environmental sample and information collection in a manner that minimizes public information collection burden compared to burden anticipated if these projects were incorporated directly into either the NCS Vanguard or Main Study.

Frequency of Response: Annual [As needed on an on-going and concurrent basis].
Affected Public: Members of the public, researchers, practitioners, and other health professionals. *Type of Respondents:* Women of child-bearing age, fathers, public health and environmental science professional organizations and practitioners, and schools and child care organizations. These include both persons enrolled in the NCS Vanguard Study

and their peers who are not participating in the NCS Vanguard Study. *Annual reporting burden:* See Table 1. The annualized cost to respondents is estimated at: \$780,000 (based on \$10 per hour). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

| Table 1. Estimated Annual Reporting Burden Summary, Environmental Science | | | | | |
|---|---|--|---|--|--|
| Data Collection Activity | Type of Respondent | Estimated Number of Respondents | Estimated Number of Responses per Respondent | Average Burden Hours Per Response | Estimated Total Annual Burden Hours Requested |
| Home Air | NCS participants | 4,000 | 1 | 1 | 4,000 |
| | Members of NCS target population (not NCS participants) | 4,000 | 1 | 1 | 4,000 |
| Home Water | NCS participants | 4,000 | 1 | 1 | 4,000 |
| | Members of NCS target population (not NCS participants) | 4,000 | 1 | 1 | 4,000 |
| Home Dust | NCS participants | 4,000 | 1 | 1 | 4,000 |
| | Members of NCS target population (not NCS participants) | 4,000 | 1 | 1 | 4,000 |
| School and Child Care Facility Air | NCS participants | 4,000 | 1 | 1 | 4,000 |
| | Members of NCS target population (not NCS participants) | 4,000 | 1 | 1 | 4,000 |
| School and Child Care Facility Water | NCS participants | 4,000 | 1 | 1 | 4,000 |
| | Members of NCS target population (not NCS participants) | 4,000 | 1 | 1 | 4,000 |
| School and Child Care Facility Dust | NCS participants | 4,000 | 1 | 1 | 4,000 |
| | Members of NCS target population (not NCS participants) | 4,000 | 1 | 1 | 4,000 |
| Small, focused survey and instrument design and administration | NCS participants | 4,000 | 2 | 1 | 8,000 |
| | Members of NCS target population (not NCS participants) | 4,000 | 2 | 1 | 8,000 |
| | Health and Social Service Providers | 2,000 | 1 | 1 | 2,000 |
| | Community Stakeholders | 2,000 | 1 | 1 | 2,000 |
| Focus groups | NCS participants | 2,000 | 1 | 1 | 2,000 |

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|---|---|--|---|--|--|
| Data Collection Activity | Type of Respondent | Estimated Number of Respondents | Estimated Number of Responses per Respondent | Average Burden Hours Per Response | Estimated Total Annual Burden Hours Requested |
| | Members of NCS target population (not NCS participants) | 2,000 | 1 | 1 | 2,000 |
| | Health and Social Service Providers | 2,000 | 1 | 1 | 2,000 |
| | Community Stakeholders | 2,000 | 1 | 1 | 2,000 |
| Cognitive interviews | NCS participants | 500 | 1 | 2 | 1,000 |
| | Members of NCS target population (not NCS participants) | 500 | 1 | 2 | 1,000 |
| Total | | 69,000 | | | 78,000 hrs |

REQUEST FOR COMMENTS: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Sarah L. Glavin, Deputy Director, Office of Science Policy, Analysis and Communication, National Institute of Child Health and Human Development, 31 Center Drive Room 2A18, Bethesda, Maryland, 20892, or call non-toll free number (301) 496-1877 or E-mail your request, including your address to glavins@mail.nih.gov.

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: March 6, 2012

Sarah L. Glavin, Ph.D.

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National Institute of Child Health and Human Development

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